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Dated: July 12, 2010 Signature: / Thomas W. Humphrey /
(Thomas W. Humphrey)

Docket No.: LF-231
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Charles S. Neer

Appeal No. 2010-009039

Application No.: 10/749,894

Confirmation No.: 8901

Filed: December 31, 2003

Art Unit: 3767

For: Injector with changeable syringe constants

Examiner: Maria E. Doukas

REPLY BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

As required, this reply brief is being filed in response to the Examiner's Answer mailed March 11, 2010.

Rejections under 35 USC 101

The Examiner's Answer states at page 3 that the rejection of claims 32 and 35-40 has been overcome by the entry of the amendment submitted by Applicant on July 30, 2009. However, on page 4 of the Examiner's Answer, the Examiner maintains a rejection under 35 USC 101 which is identical in form to the rejection made in the Final Action issued by the Examiner which is subject to the present appeal. Applicant believes the Examiner's repetition of a rejection under Section 101 is in error and that the Examiner intends to withdraw this rejection.

However, in the event this rejection is intended to be maintained, Applicant submits that the premise of the Examiner's rejection is flawed and cannot be maintained in view of the Supreme Court's decision issued June 28, 2010 in the case of *In re Bilski*, which reverses the specific point of the Federal Circuit opinion which is relied upon by the Examiner. Namely, the Examiner asserts that the Federal Circuit's opinion requires a "specialized, limited meaning" of a

method claim for it to be statutory under Section 101. However, the Supreme Court opinion issued June 28, 2010 holds that the “machine or transformation” test recited by the Federal Circuit is not the exclusive test for a patentable method, and remands the matter for further proceedings. See, Slip Opinion at 7: “The Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test.” The Examiner’s rejection is premised upon an exclusive requirement that a method be “(1) tied to a particular machine or apparatus, or (2) transform[ing] a particular article to a different state or thing”; thus, the Examiner’s rejection must be withdrawn because this ‘requirement’ does not exist based on the holding of the Supreme Court issued June 28, 2010. Moreover, as explained in Applicant’s response of July 30, 2009, even the ‘machine or transformation’ test is satisfied by the amended form of the claims which has now been entered by the Examiner.

Accordingly, the Examiner’s rejection under 35 USC 101 must be withdrawn.

Rejection under 35 USC 103

The Examiner’s Answer maintains the Examiner’s rejection of the claims as obvious under 35 USC 103. In the Examiner’s reply to Applicant’s brief, the Examiner maintains the position that a combination of the Hochman and Koenig prior art would lead to the entry of parameters using a ‘service mode’ of an injector. Specifically, as argued at page 13, the Examiner states that “[a]lthough Hochman does not explicitly teach the user inputting syringe constants into the storage of memory 160, Hochman does teach that the storage contains physical characteristics about the syringe ... It is inherent that at one point these particular physical characteristics of the syringe must have been input by a user in order for them to be within the memory’s database.” Later on page 14 the Examiner states that “even if the memory data bank of syringe constants of Hochman was created at a factory and put into non-volatile memory as applicant argues, this would still meet the claims as presented. The step of ‘entering a mode of the injector system that permits the use of service-related functions’ is not limited by claim language to this step being performed in a clinical setting ... When the infusion system is produced in the factory and loaded with the memory, the ‘service mode’ can be the mode utilized to initially program the memory of the system that stores the database of syringe information.”

Applicant submits that the Examiner's analysis cited above is fatally flawed for the reason that the pre-programming of an injector with syringe constants need not involve entry of those constants with any mode of the injector. Rather, as noted in the Background of the present application, a typical injector system has "firmware" containing the syringe parameters, and these parameters are changed by installing a new erasable/programmable read-only memory (EPROM) into the injector. An EPROM is typically programmed by a programmer station which directly "burns" firmware into the EPROM from, e.g., a desktop PC using a PROM burner. This operation does not involve the injector at all. The Examiner has not shown that the combination of the Hochman and Koenig prior art would not use this well known method to change injector parameters, i.e., that it would not use a PROM burning station, and not an injector, to create new firmware with updated parameters. The Examiner may not, therefore, assume that parameters in an injector must be there because a user typed them into a syringe interface. In fact, as stated by the Background of the present application, what is known is to change syringe parameters via an EPROM substitution, in which case those parameters are never typed in to the injector interface.

Applicant thus resubmits that the Examiner's obviousness rejection must fail, as the Examiner has not shown any prior art that suggests or allows for the entry of syringe parameters in a service mode of the injector system – but rather has only shown or suggested the changing of an injectors parameters by the substitution of EPROM. Furthermore, the Examiner has not explained a departure from the known prior art to provide such a function.

A petition for extension of time is necessary to accompany this communication, please consider this paper a petition for such an extension of time. The undersigned will provide authorization to charge a credit card in the EFS-WEB transmittal for the appropriate extension of time fee.

Applicant believes no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 23-3000, under Order No. LF-231 from which the undersigned is authorized to draw.

Dated: July 12, 2010

Respectfully submitted,

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